

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ) 3:09-md-02100-DRH-
(DROSPIRENONE) MARKETING, SALES) PMF
PRACTICES AND PRODUCTS LIABILITY)
LITIGATION) MDL No. 2100

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 51

**Regarding Motions to Exclude Testimony of
Dr. Bercy-Roberson and of Dr. Disciullo
(MDL 2100 Docs. 2110 and 2017)**

I. INTRODUCTION

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (Bayer) move to exclude certain testimony of plaintiffs' experts, Gabrielle Bercy-Roberson, M.D., (Doc. 2110) and Anthony Disciullo, M.D., (Doc. 2017), as Bayer believes their purported opinions fail to meet the requirements for admissibility under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993). Familiarity with the underlying proceedings is presumed. For the following reasons, the Court **DENIES** Bayer's motions (Docs. 2110 and 2017).

II. BACKGROUND

This multidistrict litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.¹ YAZ and Yasmin, which are manufactured, marketed, and sold by Bayer, are members of a class of prescription medicines known as combined hormonal oral contraceptives (COCs), which contain an estrogen and a progestin component (Doc. 2090, p. 6). The vast majority of COC's, including YAZ and Yasmin, contain the same type of estrogen – ethinyl estradiol (EE) (Doc. 2090, p. 6).² In contrast to estrogen, the progestins in COCs are of many types. The progestin in YAZ and Yasmin is a newer type of progestin known as drospirenone (DRSP) (Doc. 2090, p. 6).

DRSP-containing COCs are known as “fourth-generation” COCs (classified by the type of progestin used) (Doc. 2090, pp. 6-5). COCs containing earlier developed progestins are categorized as “first-generation,” “second-generation,” and “third-generation” (Doc. 2090, p. 6). First-generation COCs contain the progestin norethynodrel (Doc. 2090, p. 6) Second-generation COCs contain the progestin Levonorgestrel (LNG) and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate (Doc. 2090, p. 6).

¹ This MDL relates to other oral contraceptives that, like YAZ and Yasmin, contain drospirenone. However, YAZ and Yasmin are the subject drugs involved in the pending bellwether trials.

² YAZ and Yasmin differ in their dosing schedule and the amount of estrogen they contain. The Food and Drug Administration (FDA) approved YAZ and Yasmin as oral contraceptives in 2006. The FDA subsequently approved YAZ and Yasmin as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive and as a treatment for premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive.

It is generally accepted that there is an increased risk of venous thromboembolic (VTE) disease (disease relating to blood clotting in the veins) in COC users (Doc. 2102-14, p. 5; Doc. 2090-2, p. 2). It is also generally accepted that second-generation COCs (LNG-containing COCs) are considered to have a low risk for VTE disease (Doc. 2102-14 p. 6). Because the VTE risk associated with second-generation COCs is relatively low, LNG-containing COCs are often selected as a reference treatment in comparative studies evaluating whether there is an association between third-generation COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-4) and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-14 pp. 5-6). In the mid-1990s, various reports indicated that users of third-generation COCs were at higher risk of VTE disease than users of second-generation COCs (Doc. 2090-2, p. 2).

At issue in this litigation, is the safety of DRSP-containing COCs and whether DRSP use is associated with a higher risk of VTE disease. Specifically, Plaintiffs contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With regard to the safety of YAZ and Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life threatening thrombosis complications, including deep vein thrombosis (DVT) (a blood clot formation in one of the body's deep veins) and pulmonary embolism (a clot formation that travels to the lungs). Instantly, Bayer seeks exclusion of certain

opinions of two trained obstetrician-gynecologists (OB/GYNs) plaintiffs proffer to testify generally as physicians. Bayer argues plaintiffs tender them to offer opinions that are either outside their area of expertise, not the proper subject of expert testimony, or both (See Docs. 2110, 2017; Bayer's Replies, Docs. 2141, 2127). The Court, having carefully reviewed the record, is satisfied plaintiffs have carried their burden of demonstrating that both of the challenged witnesses possess the requisite qualifications to testify as to the disputed statements.

III. LEGAL STANDARD

A. Generally

FEDERAL RULE OF EVIDENCE 702, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), govern the admissibility of expert testimony. The *Daubert* standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.137, 141 (1999)). Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. *Daubert* clarified Rule 702 charges the district court with the task of ensuring expert testimony is both relevant and reliable. *Daubert*, 509 U.S. at 589.

Courts in the Seventh Circuit conduct a three-step analysis under *Daubert*.

Ervin v. Johnson & Johnson, Inc., 492 F.3d 901, 904 (7th Cir. 2007).³ First, the district court must determine whether the person whose testimony is offered is in fact an expert, as codified in Rule 702 through “knowledge, skill, experience, training, or education.” *Id.* (citing Fed. R. Evid. 702). Notably, although “extensive academic and practical expertise” sufficiently qualify a potential witness as an expert, *Bryant v. City of Chicago*, 200 F.3d 1092, 1098 (7th Cir. 2000), “Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience,” *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 591 (7th Cir. 2000). *Smith*, 215 F.3d at 718 (citing *Kumho*, 526 U.S. at 156 (“[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”)).

Secondly, the district court must determine the expert’s reasoning or methodology is reliable. *Ervin*, 492 F.3d at 904; see *Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir. 2004) (citing *Kumho*, 526 U.S. at 147). Specifically, the testimony must have a reliable basis in the knowledge and experience of the relevant discipline, *Kumho*, 526 U.S. at 149 (internal quotations removed), consisting in more than subjective belief or unsupported speculation. *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002); *Daubert*, 509 U.S. at 590.

³ The Court notes the Seventh Circuit has also described the *Daubert* analysis as a two-step process. See *Chapman v. Maytag Corp.*, 297 F.3d 682, 686 (7th Cir. 2002). However, as *Chapman* simply combines the first two steps described in *Ervin* as a single test of reliability, whether the analysis is described as a three-step or two-step process does not substantively change the Court’s analysis.

Further, as to reliability, *Daubert* provided the following non-exhaustive list of relevant factors: “(1) whether the scientific theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory has been generally accepted in the scientific community.” *Ervin*, 492 F.3d 901, 904 (7th Cir. 2007) (citing *Daubert*, 509 U.S. at 593-94). However, there is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be “tied to the facts” of the particular case. *Kumho*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 591); *see also Chapman*, 297 F.3d at 687. Thus, “the role of the court is to determine whether the expert is qualified in the relevant field and to examine the methodology the expert has used in reaching his [or her] conclusions.” *Smith*, 215 F.3d at 718 (citing *Kumho*, 526 U.S. at 153).

The district court possesses “great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable.” *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) (citing *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007)). Accordingly, the court’s gatekeeping function requires focus on the expert’s methodology; “[s]oundness of the factual underpinnings of the expert’s analysis and the correctness of the expert’s conclusions based on that analysis are factual matters to be determined by the trier of fact.” *Smith*, 215 F.3d at 718 (citing *Daubert*, 509 U.S. at 595; *Walker*, 208 F.3d at 587).

Resolution of an expert’s credibility or the correctness of his or her theories is left to the jury’s determination after opposing counsel has cross-examined the

expert at issue. *Id.* (citing *Walker*, 208 F.3d at 589-90). Thus, “[i]t is not the trial court’s role to decide whether an expert’s opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound.” *Id.* (citing *Kumho*, 526 U.S. at 159 (Scalia, J., concurring) (stating that the trial court’s function under *Daubert* is to exercise its discretion “to choose among reasonable means of excluding expertise that is fausse and science that is junky”)). However, as an expert must explain the methodologies and principles that support his or her opinion, he or she cannot simply assert a “bottom line” or *ipse dixit* conclusion. *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) (quoting *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010)).

Lastly, the district court must consider whether the proposed testimony will assist the trier of fact in its analysis of any issue relevant to the dispute. See *Smith*, 215 F.3d at 718; *Chapman*, 297 F.3d at 687; *Daubert*, 509 U.S. at 592. It is crucial that the expert “testify to something more than what is ‘obvious to the layperson’ in order to be of any particular assistance to the jury.” *Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 871 (7th Cir. 2001) (quoting *Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998)). However, the expert need not have an opinion as to the ultimate issue requiring resolution to satisfy this condition. *Smith*, 215 F.3d at 718 (citing *Walker*, 208 F.3d at 587).

B. Physician Testimony

Indisputably, a medical degree does not qualify a doctor to opine on all medical subjects. *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (citing *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212 (7th Cir. 1990)). However, the Seventh Circuit recognizes that often a “physician in general practice is competent to testify about problems that a medical specialist typically treats.” *Id.* (citing 29 Wright & Gold, Federal Practice and Procedure, § 6265 (1997); *Doe v. Cutter Biological, Inc.*, 971 F.2d 375, 385 (9th Cir. 1992) (“The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor.”); *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 978-79 (6th Cir. 2004); *United States v. Viglia*, 549 F.2d 335, 336 (5th Cir. 1977) (holding that a pediatrician who had degrees in medicine and pharmacology but no experience in treating patients in obesity had sufficient knowledge, training, and education to testify regarding drug’s effect on obese persons)). Thus, courts must individually evaluate each conclusion drawn to determine whether the purported expert “has the adequate education, skill, and training to reach them.” *Id.*

I. ARGUMENT AND ANALYSIS

II. Motion to Exclude the Testimony of Dr. Gabrielle Bercy-Roberson (Doc. 2110) and Motion to Exclude the Testimony of Dr. Anthony Disciullo (Doc. 2017)

1. Daubert Analysis Generally

a. Dr. Gabrielle Bercy-Roberson

i. Qualifications

The following qualifications are relevant to all statements of Dr. Bercy-Roberson for which Bayer seeks exclusion. Dr. Bercy-Roberson is a board certified OB/GYN. She earned a Doctorate of Medicine with Distinction in Research from the University of Rochester School of Medicine and Dentistry in 1993. She earned a Master in Public Health from the Harvard University School of Public Health in 1992. Dr. Bercy-Roberson holds a license to practice medicine in the Commonwealth of Massachusetts (*See Doc. 2124-2*). Additionally, Dr. Bercy-Roberson has a level I certification in Clinical Investigation. She is also pursuing an advanced certificate in Clinical Investigation through the Harvard Catalyst (*See Doc. 2124-1*). Further, she currently serves as the Clinical Director of Women's Health Services at the Martha Elliot Health Center in Jamaica Plain, Massachusetts and at the Center for Women's Health in Dorchester, Massachusetts.

She presently serves as an attending physician at four hospitals in and around Boston, Massachusetts (*See Doc. 2124-2*). Dr. Bercy-Roberson states, "[a]pproximately 20 percent of [her] clinical practice at the Martha Elliot Health

Center/Children's Hospital of Boston is focused on family planning and contraceptive counseling" (Doc. 2124-1, p. 2). Further, "[she] provide[s] direct supervision of the family planning program which had over 2000 contraceptive counseling visits last year" (Doc. 2124-1, p. 2). Additionally, Dr. Bercy-Roberson serves on numerous medical boards, has held multiple academic appointments, and received various medical honors and awards (See Doc. 2124-2).

ii. Reliability

The following is pertinent to the reliability of all Dr. Bercy-Roberson's statements for which Bayer seeks exclusion. In forming the statements currently at issue, Dr. Bercy-Roberson consulted the following:

[R]eports of clinical trials and investigations conducted by [Bayer]; literature reports, New Drug Applications (NDA) to the [FDA] and related materials, including the Medical Officer reviews and approvable packages; the original Yaz and Yasmin labels and subsequent revisions thereto; regulatory documents and communications by and between Bayer and regulatory authorities both within and outside the United States; marketing, sales and promotional materials relative to the Yaz and Yasmin products and other internal Bayer documents and numerous internal communications by and amongst Bayer employees.

(Doc. 2124-1, p. 2). Additionally, she surveyed relevant medical literature concerning the history and development of COCs generally, and specifically the "more recently developed progestins, including Cyproterone Acetate (CPA) as well as [DRSP]" (Doc. 2124-1, p. 2). Moreover, Dr. Bercy-Roberson cites to her "education, training, twenty-five years of clinical practice and experience in the fields of obstetrics, gynecology and public health as well as the relevant published

medical and scientific literature," as forming the basis of her opinions (Doc. 2124-1, p. 2).

iii. Assistance to Trier of Fact

The Court finds all Dr. Bercy-Roberson's opinions offer assistance to the trier of fact in its analysis of issues relevant to the dispute, as her testimony encompasses medical opinions and observations not obvious to a lay-person. Thus, the Court will only independently analyze whether Dr. Bercy-Roberson is qualified to categorically opine as to the disputed statements and the reliability of those statements.

b. Dr. Anthony Disciullo

i. Qualifications

The following qualifications are relevant to all statements of Dr. Disciullo for which Bayer seeks exclusion. Dr. Disciullo is a board certified OB/GYN who has practiced in the Boston area since 1975 (Doc. 2100-1, p. 2). He received a Bachelor of Arts in Biology from Boston College in 1964, and a Doctorate of Medicine from New York Medical College in 1968. He has held numerous academic appointments, including his current position as Assistant Clinical Professor of Obstetrics, Gynecology, and Reproductive Biology at the Harvard Medical School. Dr. Disciullo is an attending physician at four Boston area hospitals (Doc. 2100-1, pp. 23-24). His practice is limited to gynecology with a focus on laparoscopic and pelvic reconstructive procedures (Doc. 2100-3, p. 87-88: 24-25, 1-3). According to Dr. Disciullo, a "considerable portion" of his

practice requires him to prescribe hormonal contraception (HC) in addition to COCs (Doc. 2100-1, p. 2). Additionally, Dr. Disciullo has received several awards, conducted numerous research studies, co-authored various medical journal articles, and authored educational texts (*See Doc. 2100-1*).

ii. Reliability

The following is pertinent to the reliability of all Dr. Disciullo's statements for which Bayer seeks exclusion. Dr. Disciullo states his opinions "are based on the materials referenced throughout the body of [his] report as well as [his] clinical training, education and background knowledge of the subject matter" (Doc. 2100-1, p. 2). Additionally, Dr. Disciullo cites to an expansive list of medical literature, clinical study reports, published studies corresponding to clinical reports, deposition transcripts and exhibits, and other YAZ and Yasmin-related materials as forming the basis of his opinions (*See Doc. 2100-1, pp. 13-22*).

iii. Assistance to the Trier of Fact

The Court finds all Dr. Disciullo's statements offer assistance to the trier of fact in its analysis of issues relevant to the dispute, as his testimony encompasses medical opinions and observations not obvious to a lay-person. Thus, the Court will only independently analyze whether Dr. Disciullo is qualified to opine as to the disputed statements and the reliability of those statements.

2. *Daubert Applied to Specific Statements*

i. *Statements Bayer Argues Require Exclusion*

1. *Safety Opinions*

a. *Dr. Bercy-Roberson's Safety Opinions Based on Epidemiology*

Bayer argues the Court must exclude Dr. Bercy-Roberson's statement that YAZ and Yasmin are "not reasonably safe alternatives to other forms of hormonal contraception," as she bases this opinion on epidemiological studies she is allegedly unqualified to analyze and interpret (Doc. 2110, p. 3) (citing Doc. 2110-2, p. 10). Bayer cites to Dr. Bercy-Roberson's statement that she is not an epidemiologist for its contention that she is incapable of analyzing the epidemiological studies forming the basis of her opinion (Doc. 2110, p. 3) (citing Doc. 2110-1, p. 14: 14-16). Further, Bayer argues Dr. Bercy-Roberson is unqualified to opine in this manner as during a deposition she could not "accurately define" the term "relative risk;" a concept underlying reports on which Dr. Bercy-Robertson relies (Doc. 2110, p. 3) (citing Doc. 2210-1, p. 305: 11-19). Thus, Bayer argues Dr. Bercy-Roberson does not possess the specialized epidemiological knowledge required of her purported opinion (Doc. 2110, pp. 3-6).

Plaintiffs respond that Dr. Bercy-Roberson need not possess specialized epidemiological training to read and understand epidemiological studies published in medical journals intended for physicians of varying specialties (Doc. 2124, p. 9). As a frequent prescriber of contraceptives, plaintiffs argue Dr. Bercy-

Roberson must assess the safety of various contraceptives based on various literature, including epidemiological publications, to better inform her patients concerning potential drug-related risks (Doc. 2124, p. 10). Thus, plaintiffs argue, as they do not proffer Dr. Bercy-Roberson as an epidemiologist, but as a medical doctor and clinician tasked with assessing relative safety risks of various contraceptives, her statement concerning the relative safety of Yazmin and Yaz is properly based on her education and experience (Doc. 2124, pp. 9-11).

b. Dr. Disciullo's Safety Opinions Based on Epidemiology

Bayer argues Dr. Disciullo is not qualified to opine that YAZ and Yasmin are “not reasonably safe alternatives to other forms of hormonal contraception” (Doc. 2017, p. 3) (citing Doc. 2017-2, p. 7). Similarly to Dr. Bercy-Roberson, Bayer cites Dr. Disciullo’s alleged inability to explain epidemiological concepts underlying the reports on which he relies. For example, at Dr. Disciullo’s deposition, when Bayer asked, “did you personally evaluate the Lidegaard re-analysis in detail yourself?” Dr. Disciullo replied, “[s]o this gets into an area that I have no expertise, so I prefer not to answer” (Doc. 2017, p. 4) (citing Doc. 2017-1, p. 49: 3-8). Bayer argues Dr. Disciullo is not qualified to opine based on epidemiological studies if he cannot explain their underlying methodology. Thus, Bayer argues, as Dr. Disciullo bases his opinion as to the safety of YAZ and Yasmin on “the totality of the evidence,” “plaintiffs cannot carry their burden of establishing that Dr. Disciullo is an expert in epidemiology” (Doc. 2017, p. 4).

Plaintiffs respond Dr. Disciullo may opine as to the safety of YAZ and Yasmin despite his lack of expertise in the area of epidemiology, as they do not proffer him as an epidemiologist (Doc. 2100, p. 10). Dr. Disciullo's opinions are based, as are Dr. Bercy-Roberson's, on studies published in medical journals meant for the consumption of physicians in general. Dr. Disciullo's thirty years of clinical practice, plaintiffs' argue, qualify him to opine as to the safety of YAZ and Yasmin, based on medical studies, as he opines concerning the safety of various prescriptions on a regular basis (Doc. 2100, p. 10). As a clinician, Dr. Disciullo reads studies concerning the safety of various medications, presumably all based on underlying epidemiological studies, to inform his decisions.

Moreover, plaintiffs cite to Dr. Disciullo's explanation of the underlying reasoning of his opinions as support for its contention his opinions are not mere "bottom line" or *ipse dixit* conclusions. For example, plaintiffs state, Dr. Disciullo states in his report, regarding the European Active Surveillance Study (EURAS) and Ingenix studies, "[i]t should be noted that the EURAS study employed no exclusionary criteria. The net effect of this total lack of exclusionary criteria is to 'dilute' the ability of investigators to detect any increase in risk of VTEs between the cohorts, which provides an explanation for this study's finding of an overall thrombosis rate of 9.1::10,000 women years" (Doc. 2100, p. 11) (citing Doc. 2100-1, p. 6). Thus, Plaintiffs cite to this and similar portions of Dr. Disciullo's report explaining the basis for his contentions, in support of Dr. Disciullo's qualifications to opine as to YAZ and Yasmins' safety (Doc. 2100, pp. 11-12).

**i. Safety Opinions Based on Epidemiology
Permissible Under *Daubert***

1. Dr. Bercy-Roberson

a. Qualifications

The Court reincorporates Dr. Bercy-Roberson's general qualifications listed previously. Importantly, the Court notes, a physician of general expertise is often qualified to opine as to matters of a specialized medical nature. Thus, although Dr. Bercy-Roberson's general opinion as to the relative safety of YAZ and Yasmin is founded in part on epidemiologically based medical journal articles, her years of training and experience as an OB/GYN qualify her to opine in this manner. A reputable medical journal intended for the consumption of physicians of varying specialties published the epidemiological studies on which she bases her opinion. Specialized knowledge of the epidemiological terms underlying the articles, such as the exact definition of "relative risk," is unnecessary to qualify Dr. Bercy-Roberson to opine in this manner.

Plaintiffs do not proffer Dr. Bercy-Roberson as epidemiologist, but as an OB/GYN tasked with prescribing contraceptives to patients on a regular basis. This frequent task incites her to inform herself as to the relative risks and benefits of the contraceptive she prescribes. The reading of medical journal articles based on epidemiological studies help inform her decisions. Thus, Dr. Bercy-Roberson's years of clinical experience, education, and skill qualify her to opine generally as to the safety of YAZ and Yasmin based on the reading of epidemiologically based medical journal articles.

b. Reliability

Dr. Bercy-Roberson's method of forming her opinions is reliable as based on epidemiologically based journal articles published in reputable sources, such as the *British Medical Journal (BMJ)*, as well as medical studies and FDA-related documents. Moreover, her years of education and clinical work provide her with the experience to interpret these articles and studies and explain their findings from the perspective of a practicing OB/GYN, an admittedly different perspective from that of an epidemiologist. Dr. Bercy-Roberson's method of reading various medical articles and studies to obtain knowledge concerning safety risks of various contraceptives is reliable as it is the generally accepted method of evaluating the safety risks of various drugs within the medical field. The Court does not comment as to the correctness of Dr. Bercy-Roberson's epidemiologically based safety opinions. However, the Court finds Dr. Bercy-Roberson's bases these opinions on a reliable methodology.

2. Dr. Anthony Disciullo

a. Qualifications

The Court applies the same reasoning as stated above in finding Dr. Disciullo similarly qualified to opine as to the safety of YAZ and Yasmin based on epidemiological studies published in medical journals. Additionally, his specific thirty years of experience as an OB/GYN and significant clinical trial work qualify him to testify, from a clinical perspective, as to the safety of YAZ and Yasmin based on epidemiological studies.

b. Reliability

As Dr. Bercy-Roberson and Dr. Disciullo base their opinions on the same methodology, the Court finds Dr. Disciullo's statements similarly reliable. Further, the Court finds Dr. Disciullo more than adequately explains the basis of his opinions in his report. To the extent Bayer argues Dr. Disciullo does not comprehend the epidemiological reports on which he relies; it will be able to attack his credibility on cross-examination. However, as Dr. Disciullo bases his opinions on a reliable methodology, his testimony is proper.

c. Dr. Bercy-Roberson's Safety Opinions Based on Pharmacology or Hematology

Bayer also objects to specific statements of Dr. Bercy-Roberson concerning the safety of YAZ and Yasmin as pharmacological and hematological opinions Dr. Bercy-Roberson is unqualified to offer (Doc. 2110, p. 6). Specifically, Bayer argues Dr. Bercy-Roberson's statement that "the [DRSP COCs] is a defective product because of the high amounts of estrogen that the women are being exposed to," requires exclusion, as she is unqualified to opine concerning pharmacology (Doc. 2110, p. 7) (citing Doc. 2110-2, p. 10). In a similar vein, Bayer seeks exclusion of Dr. Bercy-Roberson's statement that, "very high levels of [sex hormone binding globulin (SHBG)] were seen in studies that [she] reviewed as well as well as [activated protein C resistance (APC^{res})]," which she links to an increased risk of venous thromboembolism (VTE) (Doc. 2110, p. 7) (citing Doc. 2110-2, p. 10). Bayer argues Dr. Bercy-Roberson's statement is improper, as she is not qualified to opine as to hematology (Doc. 2110, p. 7).

Additionally, Bayer argues Dr. Bercy-Roberson is not qualified to opine concerning the “area under the curve” (AUC), a measure of the concentration of a drug in the blood, for EE, the estrogen in most COCs (Doc. 2110, p. 8) (citing Doc. 2110-2, pp. 7-8). Bayer argues as Dr. Bercy-Roberson has never personally measured the AUC, and because she has never seen a study that used AUC as a marker in assessing VTE risk, her statements are unfounded (Doc. 2110, p. 8).⁴

Plaintiffs respond Dr. Bercy-Roberson is qualified to opine generally concerning SHBG and its relation to VTE as this connection is taught in medical school as part of an OB/GYN’s training. Thus, plaintiffs argue, Dr. Bercy-Roberson is qualified to opine generally concerning the relation of an increase in SHBG and a correlating risk of VTE (Doc. 2124, p. 15).

Further, plaintiffs respond Dr. Bercy-Roberson is qualified to testify concerning the link between YAZ and Yasmin’s total estrogenicity and VTE risk despite her lack of specialization in the areas of pharmacology and hematology (Doc. 2124, p. 14). As a daily prescriber of COCs, plaintiffs argue, Dr. Bercy-Roberson is required to read and interpret the AUC for the EE contained in COCs as this information appears on the “physician label” of the medication (Doc. 2124, p. 15). Thus, although she concedes she has never personally calculated an AUC,

⁴ Bayer cites to Dr. Bercy-Roberson’s deposition as the basis for this contention. When Bayer asked, “[d]o you know how to [measure under the curve]?”, Dr. Bercy-Roberson replied, “[i]f I was given the appropriate formula and get the sample, I could, yes.” Bayer then inquired, “But you don’t know the formula?” Dr. Bercy-Roberson replied, “I don’t have the formula at hand, no” (Doc. 2110-2, p. 49: 16-25). Dr. Bercy-Roberson went on to explain that as she does not do clinical research, she does not measure the AUC as a part of her regular practice (Doc. 2110-2, p. 50: 1-9).

plaintiffs argue Dr. Bercy-Roberson is qualified to opine as to the result of an AUC, as she does so regularly in her clinical practice (Doc. 2124, p. 15).

d. Dr. Disciullo's Safety Opinions Based on Pharmacology

Bayer argues, again similarly to Dr. Bercy-Roberson, that Dr. Disciullo is unqualified to opine as to the link between YAZ and Yasmins' total estrogenicity and VTE risk as he has neither formal qualifications nor experience with these subjects (Doc. 2017, p. 8). Bayer cites to Dr. Disciullo's deposition in support of its contention. Specifically, Bayer states, when asked, “[d]o you believe that there is a normal EE [AUC] for patients taking birth control pills?” Dr. Disciullo replied, “I’m not an expert. I don’t know if you can define normal in a situation like that. Maybe you look at averages. I’m not sure” (Doc. 2017, p. 8) (citing Doc. 2100-3, p. 289: 19-25). Bayer also argues as Dr. Disciullo concedes he is not an expert on SHBG or APC^{res}, he is unqualified to opine based on these pharmacological matters (Doc. 2017, pp. 8-9). Lastly, Bayer argues Dr. Disciullo’s opinions are unfounded as based on opinions of plaintiff experts Dr. Maggio and Dr. Stier that Dr. Disciullo did not read (Doc. 2017, p. 9).

Plaintiffs respond Dr. Disciullo’s considerable clinical experience as an OB/GYN tasked with determining embolic potential of hormonal contraceptives on a daily basis qualifies him to opine in the disputed manner. His clinical practice, coupled with his reading of the relevant medical studies and reports, plaintiffs argue, amply inform his opinions. Plaintiffs cite to Dr. Disciullo’s thirty years’ experience as a prescriber of medication, including COCs, as further qualifying

him to opine as to the use of SHBG as a marker for increased estrogenicity, as this information is generally accepted among practicing OB/GYNs (Doc. 2100, pp. 14-15). Plaintiffs state Dr. Disciullo's experience similarly qualifies him to opine as to APC^{res} and the AUC. Lastly, plaintiffs argue Dr. Disciullo is not simply "parroting" opinions of other experts, as Dr. Disciullo stated he did not read the opinions of Dr. Maggio or Dr. Stier until after forming his own opinion (Doc. 2100, p. 10) (citing 2100-3, pg. 291: 15-18).

i. Safety Opinions Based on Pharmacology or Hematology Admissible Under Daubert

1. Dr. Bercy-Roberson

a. Qualifications

Bayer's arguments concerning Dr. Bercy-Roberson's qualifications to opine in reliance on pharmacologically or hematologically based studies and reports, mirror its arguments concerning her ability to opine as to epidemiologically based articles. Thus, the Court similarly finds her years of medical training and experience qualify her to opine generally as to the relative safety of YAZ and Yasmin based on her interpretation of pharmacologically and hematologically based studies and documents.

Additionally, as to Bayer's specific argument concerning Dr. Bercy-Roberson's inability to measure the AUC, the Court finds Dr. Bercy-Roberson's qualified status does not rest on a past, personal experience measuring an AUC. As a part of Dr. Bercy-Roberson's daily practice of prescribing medicine, she is required to interpret the AUC for the EE included within the physician-intended

label of the medication. If an OB/GYN's general education and experience did not qualify them to interpret the AUC, the label would not include the AUC as guidance for prescription-related decisions. Thus, although Dr. Bercy-Roberson has never calculated an AUC herself, she is qualified to interpret one due to her years of experience as an OB/GYN. Dr. Bercy-Roberson is similarly qualified to opine generally concerning SHBG, and its relation to VTE as medical school teaches this connection as part of an OB/GYN's general medical training.

b. Reliability

Dr. Bercy-Roberson's method is reliable as she bases her opinions on a review of medical studies, articles, internal Bayer documents, and physician labels. In her report, Dr. Bercy-Roberson explains the reasoning for her conclusions and cites to the relevant reports and studies on which she relies. Dr. Bercy-Roberson explains that, as an OB/GYN, the level of estrogen in a COC affects its relative safety. Based on the studies and reports cited, Dr. Bercy-Roberson opines as to the safety of YAZ and Yasmin. Dr. Bercy-Roberson's daily practice of prescribing COCs requires her to interpret the link between total estrogenicity and VTE, in addition to the AUC for the EE contained in COCs. As she adequately explains in her report, her method of interpreting these medical calculations is reliable as based on medical studies, report, articles, physician labels, and extensive experience.

2. Dr. Disciullo

a. Qualifications

The Court reincorporates the reasoning from above as Dr. Disciullo's is similarly qualified to opine as to YAZ and Yasmins' total estrogenicity and VTE risk, notwithstanding his lack of specific training in the area of pharmacology, due to his informed reading of the relevant studies and his thirty years of clinical experience analyzing the pharmacology of prescription drugs. Similarly to Dr. Bercy-Roberson, Dr. Disciullo is capable of interpreting the AUC for EE due to his years of experience prescribing COCs. Moreover, as SHBG is a commonly used clinical parameter, as it is included in many physician-intended medication labels, Dr. Disciullo is qualified to opine as to its interpretation.

b. Reliability

Again, the Court refers to its analysis of Dr. Bercy-Roberson's methodology in analyzing the reliability of Dr. Disciullo's statements concerning the safety of YAZ and Yasmin based on pharmacological data. Specifically, the Court finds Dr. Disciullo is not simply restating the findings of other plaintiff experts. He adequately explains the reasoning of his opinions. Further, Dr. Disciullo states he did not read either Dr. Maggio's or Dr. Stier's reports before issuing his report. Bayer attacks the factual basis of Dr. Disciullo's testimony. However, this inquiry is more appropriately addressed at trial, as it is relevant to Dr. Disciullo's credibility. Thus, as Dr. Disciullo bases his informed opinions as to the safety of

YAZ and Yasmin on his clinical experience and reading of relevant studies and articles, his methodology is sound.

2. Labeling, “Ethical,” and “Other Practitioner” Opinions

a. Dr. Bercy-Roberson’s Warning Label Opinions

Bayer argues Dr. Bercy-Roberson’s statements concerning Bayer’s alleged failure to report a possible correlation between an increase of EE and an increase in VTE risk require exclusion (Doc. 2110, p. 9). For example, Dr. Bercy-Roberson remarks in her report, “in April, 2008, Bayer was in possession of the unpublished Lidegaard data indicating an increased risk, which was the same data reported in the [BMJ] article in August 2009. Apparently Bayer determined that the data was flawed and did not report the problem to the FDA nor to prescribing physicians” (Doc. 2110-2, p. 9). Bayer argues this and similar statements require exclusion as Dr. Bercy-Roberson is not an expert in FDA regulations, nor is she familiar with the labeling process concerning what a company is obligated to report to the FDA. Further, Bayer argues under *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 350-51 (2001), evidence Bayer failed to inform the FDA is inadmissible (Doc. 2110, p. 10).

Plaintiffs respond Dr. Bercy-Roberson’s opinion that Bayer did not provide physicians with complete and accurate information concerning the risks associated with YAZ and Yasmin is not an improper “regulatory opinion.” Plaintiffs contend Dr. Bercy-Roberson’s opinions, based on peer-reviewed, published medical literature, concern her belief as a practicing OB/GYN that

Bayer possessed information that would have affected her practice of prescribing COCs had she had access to it previously (Doc. 2124, pp. 17-18). Further, plaintiffs contend *Buckman* does not necessitate exclusion of Dr. Bercy-Roberson's opinions, as she is not opining as to the FDA's regulatory conduct. Dr. Bercy-Roberson's opinion that the label understates the risk of VTE as not based on all available medical evidence, plaintiffs argue, is the opinion of a practicing clinical OB/GYN based on experience and well-founded literature, it is not an opinion as to whether or not Bayer violated FDA law (Doc. 2124, p. 18).

b. Dr. Disciullo's Warning Label Opinions

Bayer argues Dr. Disciullo should not be able to opine as to "why the FDA acted in a particular manner or intimating that Bayer misled the FDA" (Doc.2017, p. 11). Specifically, Bayer seeks exclusion of Dr. Disciullo's statement that, "[t]here is evidence that the estrogen exposure reported in the labels for both YAZ and Yasmin are not accurate and understate what in fact is being delivered once the pill is ingested" (Doc. 2100-1, p. 5). Similarly, his belief that, "[b]ased on [his] reading of internal Bayer documents, it appears that the FDA, in its concern to avoid this theoretical risk, neglected a very significant risk of VTE and did not appear to focus on it likely because they considered the Yasmin product . . . to be 'low dose' pills" (Doc. 2100-1, p. 6 n. 2). Similarly to Dr. Bercy- Roberson, Bayer cites to Dr. Disciullo's lack of regulatory expertise and *Buckman* as requiring exclusion of these statements (Doc. 2017, pp. 12-13).

Plaintiffs argue that as a practicing OB/GYN prescriber of YAZ and Yasmin, Dr. Disciullo is qualified to opine as to whether Bayer provided physicians with complete and accurate information as to the drugs' risks and benefits. As Dr. Disciullo is not providing any opinion regarding the FDA regulatory process, whether Bayer violated an FDA regulatory requirement, or whether Bayer defrauded the FDA, the disputed statements are proper, plaintiffs argue. Plaintiffs state Dr. Disciullo does not require expertise in regulatory methods to comment on peer-reviewed, published medical journal articles discussing VTE risks.

Moreover, Dr. Disciullo's first-hand experience with Bayer sales representatives, according to plaintiffs, supplies a reliable basis for his opinions concerning the information Bayer supplied physicians (Doc. 2100, p. 18). Plaintiffs also clarify that Dr. Disciullo does not opine as to the appropriateness of the FDA's conduct, or as to whether Bayer violated FDA law. Thus, *Buckman* does not require exclusion of his statements (Doc. 2100, p. 19). Dr. Disciullo, plaintiffs argue, opines, "that the label understates the risk of VTE and overstates the benefits because it does not contain all of the available medical evidence." As plaintiffs state this opinion is from the perspective of a practicing clinician, not a regulatory expert, it is proper (Doc. 2100, p. 19).

c. Warning Label Opinions Admissible Under Daubert

i. Dr. Bercy-Roberson

1. Qualifications

As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are “fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] . . . and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.” *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, * 11 (E.D. Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualified to render an opinion as to the drug label’s completeness and accurateness. *See id.*

Bayer argues *Buckman* provides for exclusion of Dr. Bercy-Roberson’s at issue statements.⁵ *See Buckman*, 531 U.S. at 350-51. In *Buckman*, patients claimed to have suffered injuries from implantation of orthopedic bone screws in their spines. The patients brought suit alleging that a regulatory consultant to a manufacturer made fraudulent representations to the FDA in the course of

⁵ Although the Court finds this argument more akin to a motion *in limine*, the parties categorize it according to whether the Dr. Bercy-Roberson and Dr. Disciullo are qualified to opine in this manner. The Court analyzes it accordingly.

obtaining approval to market the screws. The Supreme Court held that state-law fraud-on-the-FDA claims were pre-empted by federal law, specifically the Federal Food, Drug, and Cosmetic Act (FDCA). *Id.* at 348. The Supreme Court found that as the FDA was empowered to punish and deter fraud against the FDA, allowance of state-law fraud-on-the-FDA claims might skew its authority. *Id.*

Buckman is a claim preemption case focusing on fraud-on-the-FDA claims, not an evidence preclusion case. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (“But the *Buckman* court specifically distinguished such ‘fraud-on-the-agency’ claims, i.e., claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles . . .”). Further, a comparison between *Buckman* and the landmark case *Wyeth v. Levine*, 555 U.S. 555 (2009), demonstrates *Buckman* is distinguishable from the case at hand. The Supreme Court made clear in *Wyeth* that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies compliance with FDA regulations. *Wyeth*, 555 U.S. at 568-73.

Plaintiffs offer the instant statements of Dr. Bercy-Roberson in demonstration of her belief that Bayer was aware of certain pre-approval cases of VTE. Dr. Bercy-Roberson opines she would have made different prescription-related decisions had Bayer previously made this information available to physicians. Thus, *Buckman* does not hold the statements inadmissible. See *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1331 (S.D. Fla. 2010) (stating, “[p]laintiffs are free to argue whether and what information, if relevant,

was withheld from them or their prescribing physicians or untimely disclosed to them or their prescribing physicians"). Thus, Dr. Bercy-Roberson's experience as a prescriber of COCs, coupled with her reading of relevant medical journals and studies, qualify her to opine in this manner.

2. Reliability

Dr. Bercy-Roberson explains in her report the reasoning for her opinion as to Bayer's alleged knowledge of pre-approval VTE risk. Dr. Bercy-Roberson states she read FDA letters, an FDA analysis of VTEs, a February 2003 article published in *BMJ*, a letter from Dr. Said Shakir submitted to the British Medical Authorities, and various other data and reports. Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is an issue left to the trier of fact's determination.

ii. Dr. Anthony Disciullo

1. Qualifications

As Bayer again makes comparable arguments concerning the exclusion of warning labels opinions of both Dr. Bercy-Roberson and Dr. Disciullo, the Court reincorporates the reasoning stated above as to Dr. Disciullo. As plaintiffs similarly clarify that Dr. Disciullo will not opine as to the FDA's conduct, *Buckman* similarly does not require exclusion of his opinions. As Dr. Disciullo is also opining from the perspective of a physician, not from that of a regulatory expert, he is qualified to opine in this manner.

2. Reliability

Dr. Disciullo bases his opinion as to Bayer's failure to provide him with all information relevant to COC prescription-related decisions on relevant medical literature he opines indicates an increased VTE risk among YAZ and Yasmin users. Additionally, his reading of internal Bayer documents informs his opinion. Moreover, Dr. Disciullo relies on his years of interactions with Bayer sales representatives. Thus, as based on extensive clinical experience and his review of the relevant record, Dr. Disciullo's opinions are reliable.

d. Dr. Bercy-Roberson's "Ethical" Opinions

Bayer further argues Dr. Bercy-Roberson improperly opines as to whether Bayer acted ethically respecting YAZ and Yasmin marketing (Doc. 2110, p. 11). For example, Dr. Bercy-Roberson's report states, "Bayer expressed more concern over the impact that this would have in the media and with regulatory authorities, than it did for patient safety" (Doc. 2110-2, p. 9). Bayer also seeks exclusion of Dr. Bercy-Roberson's statement that Bayer "lured" patients and physicians into a "false sense of security" regarding the safety of YAZ and Yasmin (Doc. 2110-2, p. 10) and that Bayer "engaged in aggressive detailing of prescribing physicians in its efforts to market its DRSP-containing COCs, including a campaign aimed at getting prescribing physicians to switch from older, safer combined hormonal contraceptives on the market" (Doc. 2110-2, p. 11). Bayer argues these opinions are speculative and improper as the subject of expert testimony, due to their non-technical, specialized, or scientific nature (Doc. 2110, p. 11-12).

Plaintiffs counter that the statements at issue do not improperly speculate as to the mindset of other practicing physicians, nor are they improper "ethics" opinions. As to Dr. Bercy-Roberson's statement concerning media impact, plaintiffs contend this is a statement formed after reading Bayer internal emails concerning the repercussions of certain events in the Netherlands reported in the *BMJ* (Doc. 2124, p. 20) (citing Doc. 2124-12, p. 2) (stating, "Don and I discussed another strategy for dealing with [BMJ]"). Plaintiffs argue Dr. Bercy-Roberson's statement is the opinion of an OB/GYN based on "sufficient expertise to understand the Significance of the *BMJ* article and to opine about Bayer's response to it" (Doc. 2124, p. 20). It is not, plaintiffs argue, an opinion as to the ethical correctness of Bayer's reaction (Doc. 2124, p. 20).

Further, as to Bayer's argument that exclusion of Dr. Bercy-Roberson's statement that Bayer "lured" physicians and patients into a "false sense of security" is required, plaintiffs counter this statement is not speculative. Plaintiffs argue it is based on Dr. Bercy-Roberson's review of Bayer's marketing documents and her own experience and expertise as a practicing OB/GYN, as she experienced first-hand the effect these marketing techniques had on her practice of prescribing COCs (Doc. 2124, p. 20). Further, plaintiffs argue, Dr. Bercy-Roberson's statement does not categorize Bayer's actions as "good" or "bad," it merely describes their effect on her clinical practice (Doc. 2124, pp. 20-21).

Finally, as to Dr. Bercy-Roberson's statement concerning "aggressive detailing of prescribing physicians," plaintiffs argue she is opining as to her

experience as a doctor "at the receiving end of this campaign," not as to Bayer's ethics or morals (Doc. 2124, p. 21). As Dr. Bercy-Roberson does not state an opinion as to "how an ethical company would act," plaintiffs contend her statement is admissible and proper as an expert opinion (Doc. 2124, p. 21).

e. Dr. Anthony Disciullo's "Ethical" Opinions

Bayer states Dr. Disciullo offers several opinions impermissibly commenting on the moral and ethical correctness of Bayer's marketing techniques. Specifically, Dr. Disciullo's statement that, "despite the fact that prescribers and users of Bayer's products depend on Bayer to communicate truthfully with them about the risks and benefits of their products, Bayer opted not to engage in such honest discourse" (Doc. 2017, p. 13) (citing 2100-1, p. 10). Bayer argues this, and opinions Dr. Disciullo stated in his deposition concerning marketing techniques Bayer employed, require exclusion as the improper subject of expert testimony due to their speculative and ethical nature (Doc. 2017, p. 14) (citing Doc. 2100-3, p. 303: 22-25) (stating, "I don't want to accuse the reps of bad conduct because I think that implies willful misbehavior, but I think they were in a way victims of their own marketing programs").

Plaintiffs respond that Bayer takes Dr. Disciullo's disputed statements out of context (Doc. 2100, p. 20). As Dr. Disciullo bases his opinion that Bayer acted inappropriately in not providing complete and accurate information on his own personal experience in addition to internal Bayer documents, plaintiffs contend, it is not speculative. Further, plaintiffs contend as Dr. Disciullo does not

improperly opine as to “how an ethical company would act,” the opinions are permissible (Doc. 2100, p. 21).

i. “Ethical” Opinions Admissible Under *Daubert*

1. Dr. Bercy-Roberson

a. Qualifications

The Court finds the disputed statements are not improper ethical opinions. Dr. Bercy-Roberson’s opinion as to Bayer’s concern with media impact is not speculative. An internal Bayer email forms the basis of this opinion. Dr. Bercy-Roberson’s experience as a physician qualifies her to opine as to her interpretation of this email. Her opinion Bayer “lured” her into a “false sense of security” is similarly non-speculative. It is based on her first-hand experience with Bayer marketing. Her opinion as to Bayer’s “aggressive detailing of prescribing physicians” is similarly based. Moreover, Dr. Bercy-Roberson does not categorize these actions as “good” or “bad,” she is simply opining as to her personal experience as an OB/GYN prescriber of COCs, including YAZ and Yasmin. Accordingly, Dr. Bercy-Roberson is qualified to opine in this manner.

b. Reliability

Dr. Bercy-Roberson’s reading of internal Bayer emails and published medical journals form the basis of her opinion. She cites to her reading of the *BMJ* article as informing her interpretation of the internal Bayer emails on which she bases her opinion as to its concern with media impact. Further, her first-hand experience as an OB/GYN provides the basis for her opinion concerning

Bayer's aggressive marketing techniques. Accordingly, these statements are based on reliable methodology and admissible.

2. Dr. Disciullo

a. Qualifications

Again, the Court finds Dr. Disciullo possesses similar qualifications to Dr. Bercy-Roberson to opine in this manner. As plaintiffs clarify, Dr. Disciullo draws on specific, personal experiences with Bayer sales representatives, his opinions are not speculative. Moreover, Dr. Disciullo does not comment on "how an ethical company would act." As Dr. Disciullo also bases his opinion on internal Bayer documents in addition to his own experience as a prescribing physician, he is similarly qualified to opine in this manner.

b. Reliability

Dr. Disciullo bases his opinions as to Bayer's conduct on the same documents and categorical experience as Dr. Bercy-Roberson's similar opinions. Accordingly, they are reliable and admissible.

f. Dr. Bercy-Roberson's "Other Practitioner" Opinions

Lastly, Bayer seeks exclusion of certain statements of Dr. Bercy-Roberson it alleges opine as to "reasons why physicians in general prescribed Yaz or Yasmin and the reasons their patients in general requested a prescription" (Doc. 2110, p. 12). Specifically, Bayer seeks exclusion of Dr. Bercy-Roberson's statement, "[t]he labels lead prescribers (like myself), and their patients, and regulatory authorities to believe the EE exposure, including the variability of delivery, was much lower

than reality" (Doc. 2110-2, p. 6). Similarly, Dr. Bercy-Roberson's statement that healthcare providers "assumed that the new drug is as safe and has more added benefits than the old drug" (Doc. 2110-2, p. 10). In addition, her statement discussed previously concerning her opinion that Bayer "lured" patients and prescribers into a "false sense of security" (Doc. 2110-2, p. 10). Finally, Bayer seeks exclusion of Dr. Bercy-Roberson's statement that, "[t]here is ample evidence that sales representatives similarly overstated the benefits of both Yasmin and Yaz products in their communications with prescribing physicians the net effect being that physicians (and their patients) were willing to switch from other, safer COCs" (Doc. 2110-2, p. 11). Bayer argues these statements are inadmissible as Dr. Bercy-Roberson is improperly speculating as to the state of mind of other physicians (Doc. 2110, p. 13).⁶

Plaintiffs respond Dr. Bercy-Roberson's statements are proper "as a prescriber of Yasmin and Yaz ... should be permitted to testify as to her own observations in her own clinical practice about the role of sales representatives, marketing materials, and how their messages influence physicians and patients" (Doc. 2124, p. 22). Plaintiffs state, "Dr. Bercy-Roberson will not testify that individual physicians would have prescribed another pill had the safety risks been manifest, but rather, her testimony concerns the importance of the benefit risk

⁶ Bayer cites to Dr. Bercy-Roberson's deposition for the basis of this contention. Bayer asked her. "[y]ou don't know to what extent any individual prescriber was actually influenced by any promotional materials of Bayer's, correct?" Dr. Bercy-Roberson replied, "[o]ther than myself? . . . No" (Doc. 2110-1, pp. 51-52: 20-25, 1-2).

calculation and the fact that a doctor needs accurate information about both the benefits and the risks in order to appropriately counsel her patients" (Doc. 2124, p. 23). Thus, plaintiffs contend Dr. Bercy-Roberson's experience as a prescriber of COCs provides a proper basis for the statements at issue (Doc. 2124, pp. 22-23).

g. Dr. Disciullo's "Other Practitioner" Opinions

Bayer seeks exclusion of certain statements of Dr. Disciullo it states also impermissibly opine as to "reasons why physicians in general prescribed Yaz and Yasmin and the reasons their patients in general requested a prescription" (Doc. 2017, p. 15). Specifically, Bayer seeks exclusion of Dr. Disciullo's statement that Bayer's "comprehensive off-label, unsubstantiated and/or otherwise misleading advertising and promotion of Yasmin and Yaz . . . encouraged prescribers/users of Yasmin/Yaz who otherwise would have used a different, safer oral contraceptive, to prescribe/use Yasmin/Yaz instead" (Doc. 2100-1, p. 9). Further, his statement that, "[w]omen and their physicians were mis-led by the promotional tactics of Bayer into thinking that these 'low dose' pills were safe or safer than older LNG-containing pills, and that the additional benefits that were promoted for both Yasmin and Yaz would justify switching the women from their existing [COC] regimens" (Doc. 2100-1, p. 5-6). Lastly, Bayer seeks exclusion of Dr. Disciullo's statement that, "the net result" of Bayer's marketing "was to encourage busy practitioners- who do not have time to conduct independent research on the safety of new products- to accommodate their patients when they would ask to be

switched to either Yasmin or Yaz" (Doc. 2100-1, p. 5). Bayer argues these statements are impermissibly speculative as Dr. Disciullo states he has never conducted a study or survey of reasons why physicians prescribed YAZ or Yasmin (Doc. 2017, p. 15-16).⁷

Plaintiffs respond that as a prescriber of YAZ and Yasmin, Dr. Disciullo can permissibly opine as to his observations of his own clinical practice concerning the role of sales representatives, marketing materials, and their influence on physicians and patients (Doc. 2100, p. 21). Plaintiffs argue these opinions are not speculative, as based on Dr. Disciullo's own experience teaching clinical OB/GYN courses at Harvard Medical School and in the administration of the OB/GYN department at Auburn Hospital. As Dr. Disciullo bases his opinions on experience, plaintiffs contend he is qualified to opine as to what information physicians consider important in the risk/benefit analysis (Doc. 2100, p. 22). Moreover, as Dr. Disciullo agrees he will not opine as to whether physicians would have prescribed another pill had the safety risks been manifest, plaintiffs contend his opinions are non-speculative and are proper (Doc. 2100, p. 23).

⁷ Bayer cites to Dr. Disciullo's deposition as support for this contention. Bayer asked, "[s]ir, have you ever conducted any type of survey or study of the reasons physicians prescribed Yasmin or Yaz?" Dr. Disciullo replied, "I have not conducted such a survey." Bayer then asked, "[h]ave you ever seen a study of the reasons a physician prescribed Yasmin or Yaz?" Dr. Disciullo replied, "I don't know if I've seen studies, but I've certainly seen articles on the subject" (Doc. 2100-3, p. 168: 17-24). Further, in response to the question, "[y]ou will not be offering opinions about why a particular physician prescribed Yasmin or Yaz to a particular patient in this case, will you?" Dr. Disciullo replied, "[t]hat's true" (Doc. 2100-3, pp. 168-69: 25, 1-5).

**i. “Other Practitioner” Opinions
Admissible Under Daubert**

1. Dr. Bercy-Roberson

a. Qualifications

Plaintiffs contend Dr. Bercy-Roberson will not speculate as to whether individual physicians would have prescribed another pill had Bayer provided the alleged knowledge at issue. Rather, plaintiffs state Dr. Bercy-Roberson’s testimony is limited to opinions concerning her own experience as a prescriber of COCs; specifically, her opinion concerning the need for access to certain benefit/risk calculations. As this opinion is based on years of personal experience and training and does not speculate as to the mindset of other physicians, Dr. Bercy-Roberson is qualified to opine in this manner.

b. Reliability

Dr. Bercy-Roberson bases her opinions on numerous articles, studies, internal Bayer documents, and personal experience. The correctness of these opinions is an issue of weight and credibility left to the jury. As Dr. Bercy-Roberson explains the basis for her opinion, based on credible sources and experience, her opinions are proper and admissible.

2. Dr. Disciullo

a. Qualifications

Once again, Dr. Disciullo is similarly qualified to opine in this manner as he also bases his opinions on his own clinical experience in addition to his experience as an educator at Harvard Medical School. Dr. Disciullo is qualified to

opine as to the information physicians deem relevant in making a risk/benefit analysis of medication. As he bases his opinions on his own experience, they are not speculative. Notably, Dr. Disciullo clarifies he will not testify as to why a particular physician prescribed YAZ or Yasmin to a particular plaintiff (*See Doc. 2100-3, pp. 168-69: 25, 1-5*). Thus, he is qualified to opine as to his own personal experience prescribing COCs.

b. Reliability

Dr. Disciullo bases his opinion on his own personal experience concerning information physicians deem important when making prescription-related decisions. Specifically, Dr. Disciullo explains the relevant criteria physicians use when evaluating prescription drugs (*See Doc. 2100-1, p. 4*). Thus, Dr. Disciullo does not state “bottom line” conclusions. He explains the reasoning of his opinions based on relevant experience and documents. Thus, as Dr. Disciullo limits his testimony to own personal experience, his opinions are the product of a reliable methodology and are admissible.

3. Certain Statements for Which Bayer Seeks Exclusion: Dr. Disciullo-Specific

a. Opinions as to Effectiveness of YAZ or Yasmin

Bayer further argues Dr. Disciullo is unqualified to opine as to whether YAZ or Yasmin effectively treat PMDD and moderate acne (Doc. 2017, p. 10). Bayer seeks exclusion of Dr. Disciullo’s opinion that, “[b]ased on [his] review of the clinical data from both the acne and PMDD trials [he could not] justify prescribing DRSP COCs in light of the marginal benefits demonstrated in the clinical trials

and based upon [his] own observation in clinical practice" (Doc. 2017, p. 10) (citing Doc. 2100-2, p. 3). Bayer argues as he cannot cite to specific literature or studies about PMDD, Dr. Disciullo is unqualified to opine in this manner.⁸

Bayer also seeks exclusion of Dr. Disciullo's opinion as to the invalidity of a study suggesting YAZ or Yasmin are more effective than other COCs in preventing pregnancy (Doc. 2017, p. 10) (citing Doc. 2100-2, p. 3). Bayer also argues, as Dr. Disciullo has never "done any analysis of the efficacy of Yaz for the treatment of acne," he cannot opine as to YAZ or Yasmin's ability to treat it (Doc. 2017, p. 10). Further, as Dr. Disciullo states he is not an expert in epidemiology, Bayer argues he is unqualified to opine as to the validity of an epidemiological study demonstrating the relative efficacy of YAZ or Yasmin to prevent pregnancy (Doc. 2017, p. 11).

Plaintiffs argue Dr. Disciullo is qualified to opine as to his belief that YAZ or Yasmin's purported ability to treat PMDD and moderate acne do not justify prescribing YAZ or Yasmin (Doc. 2100, p. 16). Plaintiffs state Dr. Disciullo's clinical experience informs his belief that COCs are not the most effective means of treating PMDD or moderate acne. Dr. Disciullo relies on his reading of relevant literature, plaintiffs argue, in addition to his daily practice of weighing the benefits and risks of prescription medications, in forming this opinion (Doc. 2100, p. 16). Moreover, plaintiffs contend, Dr. Disciullo explains that in his opinion other

⁸ Bayer cites to Dr. Disciullo's deposition as the basis of this contention. Bayer asked, "[c]an you point me to anything that I could go look up on the computer or in a library that supports your opinions that you plan to give at trial about PMDD and the effectiveness of Yaz to treat it?" Dr. Disciullo replied, "[s]itting here right now, I can't point you to anything specific" (Doc. 2100-3, p. 185: 18-24).

medication exists that more efficiently treats PMDD (Doc. 2100, p. 17). Thus, plaintiffs cite to Dr. Disciullo's years of experience prescribing YAZ or Yasmin and his knowledge gleaned from relevant literature regarding the VTE risks of hormonal COCs, as forming the basis of his opinion (Doc. 2100, p. 17).

i. Dr. Disciullo's Opinions as to Effectiveness of YAZ or Yasmin permissible Under Daubert

1. Qualifications

Dr. Disciullo's bases his opinion as to the merits of prescribing COCs to treat PMDD and moderate acne on his years of experience as a prescriber of COCs. Although Dr. Disciullo has never personally conducted an analysis of YAZ or Yasmin's effectiveness as to acne treatment, he is qualified to opine, based on relevant experience and literature, in this manner. The fact he could not, on the spot, cite to a specific study concerning the effectiveness of YAZ or Yasmin to treat PMDD does not invalidate his testimony on this subject. Dr. Disciullo cites to numerous reports and studies, in addition to his own preference as a prescriber of COCs, as forming the basis of these opinions. Accordingly, Dr. Disciullo is qualified to opine in this manner.

2. Reliability

Dr. Disciullo thoroughly explains the basis of his opinions in his report. Dr. Disciullo cites to the availability of other medication that also treat PMDD and moderate acne. Based on this availability, Dr. Disciullo believes the risks of YAZ and Yasmin outweigh the benefits. He bases this opinion on his reading of the relevant available literature concerning the safety of YAZ or Yasmin, in addition to

his own experience. Bayer is free to attack the credibility of this opinion on cross-examination. However, as Dr. Disciullo bases his opinion on his own relevant experience, in addition to medical studies and reports, it is reliable and admissible.

b. Relevancy of Testimony Concerning Dr. Disciullo's Own Practice and Patient Population

Bayer also argues certain statements of Dr. Disciullo require exclusion as irrelevant under Fed. R. Evid. 402. For example, Bayer argues Dr. Disciullo's statement, “[i]n my practice, we are regularly visited by sales reps from the various companies who are clearly attempting to encourage the use of their own companies' products, and Bayer is well-represented in this regard,” is impermissible as it does not prove or disprove any fact at issue in any plaintiff's case (Doc. 2017, p. 16). Bayer argues this and similar statements require exclusion as jurors may “improperly extrapolate Dr. Disciullo's experiences as the experiences of plaintiffs' prescribing physicians” (Doc. 2017, p. 17).

Plaintiffs contend the Court should permit Dr. Disciullo to testify in this manner, as his testimony is relevant to the dispute. As Dr. Disciullo is opining as to the relative safety of YAZ or Yasmin, plaintiffs contend, his testimony regarding his own experience with the sales tactics of Bayer representatives and its relation to his current views concerning the prescription of COCs is relevant (Doc. 2100, p. 23). Moreover, plaintiffs argue Dr. Disciullo's testimony will not cause jury confusion as he is clearly testifying as to his own personal clinical experience (Doc. 2100, p. 23).

i. Relevancy of Testimony Improper for Resolution at This Time

The Court finds resolution of the purported testimony's relevancy under Fed. R. Evid. 402 is more appropriately addressed at trial. Accordingly, the Court does not comment as to the testimony's relevancy at this time.

c. Opinions Concerning Alleged Future Damages

Lastly, Bayer argues Dr. Disciullo states impermissible opinions as to "the long term consequences of VTE," requiring exclusion under Fed. R. Evid. 403 as any marginally probative value is outweighed by "danger of unfair prejudice, confusion of the issues, or misleading [of] the jury" (Doc. 2017, p. 17). For example, Bayer seeks exclusion of Dr. Disciullo's statement that, "[a]ny woman of child bearing years who has a blood clot would be considered and treated as a 'high risk' pregnancy" (Doc. 2100-1, p. 10). Further, Bayer seeks exclusion of Dr. Disciullo's statement that patients with a history of blood clot will "inevitably be anti-coagulated prior to even minor surgical procedures, which could include any manner of gynecological surgery" (Doc. 2100-1, p. 11). In addition to Bayer's arguments concerning the prejudicial value of these statements, it also contends these and similar statements require exclusion as improper speculation concerning the long-term consequences of VTE that Dr. Disciullo's experience as a gynecological surgeon does not qualify him to testify concerning (Doc. 2017, pp. 17-18).

Plaintiffs respond Dr. Disciullo's experience treating patients with VTE qualifies him to testify as to experientially related facts and opinions regarding

future damages (Doc. 2100, pp. 23-24). Plaintiffs contend under *United States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004), Dr. Disciullo's testimony is proper as he "explain[s] how [his] experience led to the conclusion reached, why that experience [forms] a sufficient basis for the opinion, and just how that experience [is] reliably applied to the facts of the case in order to avoid sharing information that could unduly influence the jury" (Doc. 2100, p. 24). As Dr. Disciullo's explained at his deposition that, he has "to keep up with patients with [VTEs] because it happens in the course of what [he does] for a living . . . if a patient comes in and has this complicating problem, [he deals] with it in what [he feels] is the proper fashion. So for that patient [he is] the expert" (Doc. 2100, p. 24) (citing 2100-3, p. 110: 11-21). Thus, plaintiffs argue, Dr. Disciullo is qualified to opine as to the long-term consequences of VTE due to his thirty years of experience as a gynecologist and surgeon, diagnosing and counseling patients with VTE and post VTE issues (Doc. 2100, p. 25).

i. Testimony not More Prejudicial Than Probative

To the extent Bayer seeks exclusion of Dr. Disciullo's testimony as to possible future consequences of VTE under Fed. R. Evid. 403, the Court finds the evidence at issue is more probative of the issues at bar and helpful to the jury, than it is prejudicial.

ii. Testimony Concerning Alleged Future Damages Permissible Under Daubert

a. Qualifications

The Court finds Dr. Disciullo is qualified to opine as to the long-term consequences of VTE due to his experience as a gynecological surgeon. As stated throughout this Order, a physician does not require specialized, expert knowledge of a certain medical field to opine based on his or her own medical experience. Dr. Disciullo's experience treating patients suffering from VTE qualifies him to testify concerning the consequences of VTE.

b. Reliability

Dr. Disciullo bases his opinion on his own, personal experience treating patients with VTE. Thus, these opinions are not speculative as he cites how his experience led him to the disputed conclusions and can explain this connection in a way that will not confuse the jury. He links his opinions as to the effect of VTE on anti-coagulation, high-risk pregnancy, and Hormone Replacement Theory to his relevant medical experience treating gynecological patients. He cites to these effects as relevant to the risk/benefit analysis he performs when prescribing drugs. Once again, Bayer may challenge the credibility of Dr. Disciullo's opinions on cross-examination. However, as he bases his opinions on a reliable methodology, they are properly admissible.

CONCLUSION

For the foregoing reasons, the Court finds Dr. Bercy-Roberson and Dr. Disciullo qualified to opine as to the matters stated in their expert reports, as

explained and clarified in plaintiffs' responses to Bayer's motions (Docs. 2124 and 2100). Further, these opinions, as grounded in credible articles, studies, reports, internal Bayer documents, and personal experience are based on a reliable methodology. Accordingly, Bayer's arguments seeking exclusion of their opinions are relevant to the weight and credibility of the proposed testimony. As such, Bayer's motions to exclude testimony of Garbielle Bercy-Roberson, M.D., and Anthony Disciullo, M.D., are **DENIED** (Docs. 2110 and 2017).

SO ORDERED

 David R. Herndon
2011.12.16
17:27:39 -06'00'

Chief Judge
United States District Court

Date: December 16, 2011